

REMARKS

I. Procedural Matters

New Claims 59 and 60 are added. These claims were filed in a 27 December 2000 amendment but were refused entry on the grounds that they were underlined. Because the additional claims fee for those claims was submitted at the time the claims were originally filed, no additional fee is enclosed.

Claims 1 - 60 are pending.

II. Objection to the Specification

Three replacement paragraphs are submitted which update references to applications 08/905,090 and 08/732,511 to include the numbers for patents that issued and date back to the listed application numbers. Applicant respectfully submits that these references are permissible, regardless of whether the incorporated subject matter is essential or non-essential. See MPEP 608.01(p).

Marked up versions of the replacement paragraphs are included as a separate paper filed with this amendment, pursuant to 37 CFR 1.121(b)(1)(iii).

II. Claim Rejections

Claim 1, which has not been amended, includes the steps of generating a three-dimensional model of a region of interest; *determining the three-dimensional location of a physical characteristic in the region of interest using at least one probe positioned within the living body*; deforming the model to at least approximately incorporate the physical characteristic at the determined three-dimensional location; and displaying the model on a graphical display. Claims 2 - 14 are dependent on Claim 1 and thus also include these recitations.

The recited combination of steps is not found in Sheehan. As understood by Applicant, Sheehan does not use a probe positioned within the living body to determine the 3-D location of a region of interest within the living body. Sheehan is understood to describe a method for defining three-dimensional heart contours using ultrasound images of the heart taken using an ultrasound imaging transducer positioned on the chest. Accordingly, Claims 1 - 14 are not anticipated or made obvious by Sheehan.

Claim 15, which has not been amended, includes the steps of generating a three-dimensional model of at least a portion of an organ, the model including a plurality of anatomical features corresponding to anatomical features in the organ; *obtaining the relative three-dimensional locations of known anatomical features in the organ using a reference probe positioned in the organ*; deforming the model using the determined relative three-dimensional locations of the anatomical features in the organ to approximately correlate the three-dimensional locations of the anatomical features on the model to the determined locations of corresponding anatomical features in the organ; and graphically displaying the model. Claims 16 - 22 are dependent on Claim 15.

For the reasons discussed above, Sheehan is understood by Applicant to lack any teaching of obtaining the relative three-dimensional locations of known anatomical features in the organ using a reference probe positioned in the organ and deforming the model using the determined relative three-dimensional locations. Claims 15 - 22 are therefore patentable over Sheehan.

Claim 23, also un-amended, includes the steps of generating a three-dimensional model of the heart, *obtaining the relative three-dimensional locations of known anatomical features in the heart using a reference catheter positioned in the heart*; deforming the model using the determined relative three-dimensional locations of the anatomical features in the organ to approximately correlate the three-dimensional locations of the anatomical features on the model to the determined locations of corresponding anatomical features in the heart, *positioning an additional probe in a chamber*

of the heart, obtaining the relative three-dimensional location of a physical characteristic using the additional probe, and further deforming the model to approximately incorporate at least a portion of the physical characteristic. Claims 24 - 30 are dependent on Claim 23. Sheehan is understood to lack teaching or fair suggestion of the recited combination of steps, including for example those calling for obtaining the relative three-dimensional locations of known anatomical features in the heart using a reference catheter positioned in the heart, deforming the model using the determined relative three-dimensional locations, positioning an additional probe in a chamber of the heart, obtaining the relative three-dimensional location of a physical characteristic using the additional probe, and further deforming the model to approximately incorporate at least a portion of the physical characteristic. Claims 23 - 30 are patentable over this reference.

Claim 31, which also remains unamended, includes a graphical display; display software for generating a model of a region of interest and for displaying the model on the graphical display; *a probe positionable with a region in a living body corresponding to the region of interest; a localization system for determining the three-dimensional location of at least a portion of the probe when the probe is positioned in a living body, and for deriving the three-dimensional location of a physical characteristic in the region of interest from the determined three-dimensional location of the probe; and* transformation software for deforming the model to at least approximately incorporate the physical characteristic at the determined three-dimensional location. Claims 32 - 37 are dependent on Claim 31. For the reasons explained above, there is no teaching in Sheehan of the recited combination of features. Claims 31 - 38 are thus patentable over Sheehan.

Claim 38 recites a system including *a reference probe positionable within or in proximity to an organ in a living body and a localization system for determining the three-dimensional location of at least a portion of the reference probe when the probe is positioned within or in proximity to the*

organ, and for deriving the three-dimensional locations of anatomical features in the organ from the determined three-dimensional location of the reference probe, and is thus also patentable over Sheehan for reasons discussed above. Claims 39 - 47 are dependent on Claim 38 and are patentable for the same reasons.

Claim 48 recites a method of graphically displaying and dynamically correcting an image of an organ, which includes generating a graphical model of the organ; *inserting a catheter into the body and obtaining data corresponding to the location of a physical characteristic associated with the organ*; deforming the graphical model with the location data to increase the conformity of the model to the actual organ within the body; and displaying the deformed graphical model. Claims 49 - 55 are dependent on Claim 48. These claims are thus patentable for reasons similar to those set forth above.

Claim 56 is a system claim that includes *a catheter for placement into the body adjacent the organ; and means associated with the catheter for generating data related to the position of the catheter and wherein said processor utilizes said position data to deform the displayed model of the organ*. Claims 57 and 58 are dependent on Claim 56. Again, these claims are patentable given the apparent absence in Sheehan of disclosures of or fair suggestion for such features.

III. New Claims 59 and 60

New independent Claims 59 and 60 have been added. These claims were filed in a 27 December 2000 amendment but were refused entry on the grounds that they were underlined.

Claims 59 and 60 are believed patentable for reasons similar to those set forth with respect to Claims 1 - 58.

IV. Information Disclosure Statement

Applicant acknowledges the Examiner's request for additional copies of the non-patent literature submitted with the IDS mailed October 8, 1998. The

copies are enclosed, together with a copy of the Information Disclosure Statement and PTO-1449 form as originally filed on October 8, 1998. Acknowledgment of the references is respectfully requested.

Application also submits a new Information Disclosure Statement herewith.

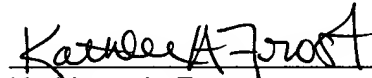
V. Conclusion

In view of the forgoing, all claims are believed allowable over the cited references. Early reconsideration and allowance of the claims is thus respectfully requested.

Respectfully submitted,
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#8

Marked Up Replacement Paragraphs

Application No. 09/128,304,

A Dynamically Alterable Three-Dimensional Graphical Model of a Body Region

Replacement paragraph for Page 3, lines 8 – 23:

U.S. Patent No. 6,216,027, "SYSTEM FOR ELECTRODE LOCALIZATION USING ULTRASOUND," [Co-pending U.S. Application No. 08/905,090, filed August 1, 1997, entitled SYSTEM FOR ELECTRODE LOCALIZATION USING ULTRASOUND,] assigned to Cardiac Pathways Corporation and incorporated herein by reference, describes a device localization system that uses one or more ultrasound reference catheters to establish a fixed three-dimensional coordinate system within a patient's heart, preferably using principles of triangulation. The coordinate system is represented graphically in three-dimensions on a video monitor and aids the clinician in guiding other medical devices, which also carry ultrasound transducers, through the body to locations at which they are needed to perform clinical procedures. The system is preferably used in the heart to help the physician guide mapping catheters for measuring electrical activity, and ablation catheters for ablating selected regions of cardiac tissue, to desired locations within the heart.

Replacement paragraph for Page 13, lines 3-10:

Another localization system useful in connection with the present invention is an ultrasound localization system described in U.S. Patent No. 6,216,027 [Application No. 08/905,090, filed August 1, 1997], entitled SYSTEM FOR ELECTRODE LOCALIZATION USING ULTRASOUND. A preferred embodiment of the present invention will be described with reference to this ultrasound localization system. It is important to note, however, that the scope of the invention is not limited to systems in which ultrasound localization is used.

Replacement paragraph for Page 57, line 12 through Page 58, line 4:

After confirming that the catheter is in contact with the wall, the user provides input to the system indicating that the catheter is in contact with the wall of a specified chamber. The operator can use a variety of methods to determine whether the probe is in contact with the endocardial surface. One such method involves observing the probe on the fluoroscope (or viewing an un-gated representation of the probe on the localization system display), simultaneously observing the patient's EKG, and determining whether the probe is pulsing with the patient's EKG. The user may also evaluate contact between the probe and the endocardial surface by feeling mechanical resistance as the catheter is advanced. Alternatively, if the probe is provided with mapping electrodes, contact with the endocardial surface may also be confirmed by monitoring EP signals from the mapping electrode(s). Rapid deflection of the EP signals indicates contact between the electrode and the endocardium. The EP signals may be monitored visually on an EP display or automatically by the system as set forth in detail in U.S. Patent No. 5,820,568, assigned to Cardiac Pathways Corporation [co-pending Application No. 08/732,511, filed October 15, 1996,] and entitled APPARATUS AND METHOD FOR AIDING IN THE POSITIONING OF A CATHETER. If the monitoring is automatic, the EP system may automatically send a signal to the transformation system that the catheter is in contact with the chamber wall.